

Food and Drug Administration will recommend that the agency also consider whether or not it should accept nonclinical laboratory studies performed by the testing facility. If such notice is sent to any other person, it shall state that it is given because of the relationship between the testing facility and the person being notified and that the Food and Drug Administration is not advising or recommending that any action be taken by the person notified.

(b) A determination that a testing facility has been disqualified and the administrative record regarding such determination are disclosable to the public under part 20 of this chapter.

§ 58.215 Alternative or additional actions to disqualification.

(a) Disqualification of a testing facility under this subpart is independent of, and neither in lieu of nor a precondition to, other proceedings or actions authorized by the act. The Food and Drug Administration may, at any time, institute against a testing facility and/or against the sponsor of a nonclinical laboratory study that has been submitted to the Food and Drug Administration any appropriate judicial proceedings (civil or criminal) and any other appropriate regulatory action, in addition to or in lieu of, and prior to, simultaneously with, or subsequent to, disqualification. The Food and Drug Administration may also refer the matter to another Federal, State, or local government law enforcement or regulatory agency for such action as that agency deems appropriate.

(b) The Food and Drug Administration may refuse to consider any particular nonclinical laboratory study in support of an application for a research or marketing permit, if it finds that the study was not conducted in accordance with the good laboratory practice regulations set forth in this part, without disqualifying the testing facility that conducted the study or undertaking other regulatory action.

§ 58.217 Suspension or termination of a testing facility by a sponsor.

Termination of a testing facility by a sponsor is independent of, and neither in lieu of nor a precondition to, pro-

ceedings or actions authorized by this subpart. If a sponsor terminates or suspends a testing facility from further participation in a nonclinical laboratory study that is being conducted as part of any application for a research or marketing permit that has been submitted to any Center of the Food and Drug Administration (whether approved or not), it shall notify that Center in writing within 15 working days of the action; the notice shall include a statement of the reasons for such action. Suspension or termination of a testing facility by a sponsor does not relieve it of any obligation under any other applicable regulation to submit the results of the study to the Food and Drug Administration.

[43 FR FR 60013, Dec. 22, 1978, as amended at 50 FR 8995, Mar. 6, 1985]

§ 58.219 Reinstatement of a disqualified testing facility.

A testing facility that has been disqualified may be reinstated as an acceptable source of nonclinical laboratory studies to be submitted to the Food and Drug Administration if the Commissioner determines, upon an evaluation of the submission of the testing facility, that the facility can adequately assure that it will conduct future nonclinical laboratory studies in compliance with the good laboratory practice regulations set forth in this part and, if any studies are currently being conducted, that the quality and integrity of such studies have not been seriously compromised. A disqualified testing facility that wishes to be so reinstated shall present in writing to the Commissioner reasons why it believes it should be reinstated and a detailed description of the corrective actions it has taken or intends to take to assure that the acts or omissions which led to its disqualification will not recur. The Commissioner may condition reinstatement upon the testing facility being found in compliance with the good laboratory practice regulations upon an inspection. If a testing facility is reinstated, the Commissioner shall so notify the testing facility and all organizations and persons who were notified, under § 58.213 of the disqualification of the testing facility. A determination that a testing facility has

Food and Drug Administration, HHS

§ 60.3

been reinstated is disclosable to the public under part 20 of this chapter.

PART 60—PATENT TERM RESTORATION

Subpart A—General Provisions

Sec.

60.1 Scope.

60.2 Purpose.

60.3 Definitions.

Subpart B—Eligibility Assistance

60.10 FDA assistance on eligibility.

Subpart C—Regulatory Review Period Determinations

60.20 FDA action on regulatory review period determinations.

60.22 Regulatory review period determinations.

60.24 Revision of regulatory review period determinations.

60.26 Final action on regulatory review period determinations.

60.28 Time frame for determining regulatory review periods.

Subpart D—Due Diligence Petitions

60.30 Filing, format, and content of petitions.

60.32 Applicant response to petition.

60.34 FDA action on petitions.

60.36 Standard of due diligence.

Subpart E—Due Diligence Hearings

60.40 Request for hearing.

60.42 Notice of hearing.

60.44 Hearing procedures.

60.46 Administrative decision.

AUTHORITY: 21 U.S.C. 348, 355, 360e, 360j, 371, 379e; 35 U.S.C. 156; 42 U.S.C. 262.

SOURCE: 53 FR 7305, Mar. 7, 1988, unless otherwise noted.

EDITORIAL NOTE: Nomenclature changes to part 60 appear at 68 FR 24879, May 9, 2003.

Subpart A—General Provisions

§ 60.1 Scope.

(a) This part sets forth procedures and requirements for the Food and Drug Administration's review of applications for the extension of the term of certain patents under 35 U.S.C. 156. Patent term restoration is available for certain patents related to drug products (as defined in 35 U.S.C.

156(f)(2)), and to medical devices, food additives, or color additives subject to regulation under the Federal Food, Drug, and Cosmetic Act or the Public Health Service Act. Food and Drug Administration actions in this area include:

(1) Assisting the United States Patent and Trademark Office in determining eligibility for patent term restoration;

(2) Determining the length of a product's regulatory review period;

(3) If petitioned, reviewing and ruling on due diligence challenges to the Food and Drug Administration's regulatory review period determinations; and

(4) Conducting hearings to review initial Food and Drug Administration findings on due diligence challenges.

(b) References in this part to the Code of Federal Regulations are to chapter I of title 21, unless otherwise noted.

[53 FR 7305, Mar. 7, 1988, as amended at 57 FR 56261, Nov. 27, 1992]

§ 60.2 Purpose.

(a) The purpose of this part is to establish a thorough yet efficient process for the Food and Drug Administration review of patent term restoration applications. To achieve this purpose, the regulations are intended to:

(1) Facilitate determinations of patent term restoration eligibility and regulatory review period length, and

(2) Ensure that parties interested in due diligence challenges will have an opportunity to participate in that process, including informal hearings.

(b) The regulations are intended to complement those promulgated by the United States Patent and Trademark Office to implement those parts of the law which are under that agency's jurisdiction. These regulations shall be construed in light of these objectives.

§ 60.3 Definitions.

(a) The definitions contained in 35 U.S.C. 156 apply to those terms when used in this part.

(b) The following definitions of terms apply to this part:

(1) The term *Act* means the Federal Food, Drug, and Cosmetic Act (secs. 201–901, 52 Stat. 1040 *et seq.* as amended (21 U.S.C. 301–392)).